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EXAMINER

SHARAREH, SHAHNAM J

ART UNIT PAPER NUMBER

1617

DATE MAILED: 06/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/991,117

Applicant(s)

FARBER, ELLIOTT

Examiner

Shahnam Sharareh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/13/2001, 2/10/2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-105 is/are pending in the application.
- 4a) Of the above claim(s) 6-76 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 77-105 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 7/22/03; 3/26/2002
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Claims 1-105 are pending.

Election/Restrictions

1. Applicant's election of species of anionic emulsifiers with acidic waxes as the emulsifier system filed on February 10, 2004 is acknowledged. Claims 1-5, 77-105 are directed towards the elected species and are under consideration. Claims 6-76 are withdrawn from further consideration because they are not directed towards the elected species.

Claim Objections

Claims 100-105 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claims 100-105 add limitations to the parent claims that already exist in the parent claims. Therefore, said claims fail to further limit the subject matter of their base claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

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patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-5, 77-105 are rejected under the judicially created doctrine of

obviousness-type double patenting as being unpatentable over claims 1-48 of U.S.

Patent No. 6,281,236 (US '236) and claims 1-34 of US Patent No. 6,329,413 (US '413).

The patented claims of US '236 and US '413 are directed to topical oil-in-water emulsions comprising allantoin, beeswax, and anionic emulsifiers, which can further contain at least one herbal extract, chelating agent, inorganic acid, emollients or a preservative, and wherein the pH of the emulsion is within the ranges of the instantly claimed pH. The instant claims are generic to the patented claims. Thus, the patented claims anticipate the instant pending claims. Accordingly, once one of ordinary skill in the art is in possession of the patented claims, it would have been obvious at the time of invention to practice the scope of instant claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 95-97 are rejected under 35 U.S.C. 102(b) as being anticipated by Minoru Kuroda et al JP 58-140013 ('JP 013) (see entire translation).

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3. The instant claims are directed to compositions comprising oil in water emulsions comprising allantoin, an anionic emulsifier, and an acidic wax adjusted to pH of about 3.0-6.0.

4. JP '013 discloses topical oil-in-water emulsions comprising allantoin (see claim 1). JP '013 also employs an acidic wax such as white vasoline, paraffin or squalane. JP '013 recites the use anionic surfactants namely sodium alkyl sulfates such as sodium lauryl sulfate may be employed in such emulsions if desired (see claims 1, the entire pages 2-3, 5-6, especially examples 1). The pH of the compositions disclosed in JP '013 ranges between 4-7, which overlaps with the instant pH ranges. Accordingly, JP '013 meets the limitations of the instant claims.

Claims 1-3, 77-78, 81-86, 95-99 are rejected under 35 U.S.C. 102(b) as being anticipated by Grollier 4,933,177 (Grollier I) or Grollier et al US Patent 4,767,618 (Grollier II).

Grollier I discloses oil-in-water emulsion compositions that contains allantoin, propylene glycol, mineral oils, fatty body wax such as carnaba wax or bees wax, thickening agents such as guar gum, alginates, methyl cellulose and starch that meet the requirement of instant carbohydrate polymers (see col 6, lines 6-60; col 6, line 6, 56, example 18, 22-, 32, 34-3623). Grollier finally claims a composition that contains various plant ingredients such as witch hazel, in combination with a fatty body, such as beeswax, a thickening agent such as a carbohydrate polymer, an emulsifer such as sodium lauryl sulfate in oil-in water emulsion. (see col 16, lines 50-64). Accordingly, Grollier I meets the limitations of the instant claims.

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Grollier II discloses oil-in-water emulsion compositions that can contain beeswax as a component, which assists oil retention (see col 6, lines 53-56; col 5, line 49). Grollier II also teaches the use of herbal components in such oil-in-water emulsions. Grollier I also teaches the use of anionic surfactants such as sodium lauryl sulfate as emulsifying agents (see col 6, lines 5-13), lanolin oil, and cod liver oil as the oil phase (see col 5, line 27-30; col 6, line 40-41), propylene glycol or cetyl alcohol as solvents (col 5, lines 5-12; col 16, lines 30-35), perfume of choice, anti-inflammatory and antiseptic such as allantoin (col 16, line 34-35), a pH modifier, antioxidants such as butyl hydroxyanisole, and preservative agents such as methyl parahydroxybenzoate (methylparaban, see RN 99-76-3), or propyl parahydroxy benzoate (propylparaben, see RN 94-13-3) (see col 6, lines 56-60; col 14, lines 20-23). Thus, Grollier II anticipates the limitations of the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 1-5, 77-86, 95-101 are rejected under 35 U.S.C. 103(a) as being unpatentable over Minoru Kuroda et al JP 58-140013 ('JP 013) (see entire translation) in view of Grollier et al US Patent 4,767,618 (Grollier II).
6. JP '013 discloses topical oil-in-water emulsions comprising allantoin (see claim 1). The emulsions of JP '013 further contain a higher fatty acid such as stearic acid (a C₁₈ organic acid) and cetyl alcohol. JP '013 also states that anionic surfactants namely sodium alkyl sulfates such as sodium lauryl sulfate may be employed in such emulsions if desired (see claims 1, the entire pages 2-3, 5-6, especially examples 1). The pH of the compositions disclosed in JP '013 ranges between 4-7, which overlaps with the instant pH ranges. In fact, JP '013 encourages the use of lower ranges of such pH for improving the stability of allantoin. The compositions taught in JP '013 don't contain beeswax and the instant herbal components such as St. Johns' wort, arnica extract or chamomile extract.
7. Grollier II discloses oil-in-water emulsion compositions that can contain beeswax as a component, which assists oil retention (see col 6, lines 53-56; col 5, line 49). Grollier II also teaches the use of herbal components in such oil-in-water emulsions. The herbal components taught by Grollier I include St. John's wort, chamomile, arnica, or witch hazel (col 3, lines 30-31, 46-56) that can be in the form of powder or extract (see col 2, lines 4-15; col 6, lines 61-64). Grollier I also teaches the use of anionic surfactants such as sodium lauryl sulfate as emulsifying agents (see col 6, lines 5-13), lanolin oil, and cod liver oil as the oil phase (see col 5, line 27-30; col 6, line 40-41),

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propylene glycol or cetyl alcohol as solvents (col 5, lines 5-12; col 16, lines 30-35), perfume of choice, anti-inflammatory and antiseptic such as allantoin (col 16, line 34-35), a pH modifier, antioxidants such as butyl hydroxyanisole, and preservative agents such as methyl parahydroxybenzoate (methylparaban, see RN 99-76-3), or propyl parahydroxy benzoate (propylparaben, see RN 94-13-3) (see col 6, lines 56-60; col 14, lines 20-23). Grollier I compositions are essentially in the form of emulsions (col 7, lines 9-21).

8. It has been held that the selection of known material based on its suitability for its intended use supported a *prima facie* obviousness determination in *Sinclair & Carroll co. V. Interchemcial Corp.*, 325 U.S. 327, 65 USPQ 297 (1945). Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the JP '013 emulsions by adding cosmetic components of interest including oil retention agents such as beeswax, and suitable herbal components of choice such as chamomile or St. John's wort, as taught by Grollier II.

9. The ordinary skill in the art would have had a reasonable expectation of success in combining the above recited components, since it has been reasoned that reading a list and selecting a known compound to meet known requirements is no more ingenious than selecting the last piece to put in the last opening in a jig-saw puzzle. *Sinclair & Carroll co.*, 325 U.S. at 335, 65 USPQ at 301. Thus, since all elements of the instant claims are taught in the cited references to be employed in oil-in-water emulsion systems combining them for their own intended use would have been *prima facie* obvious.

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10. Claims 1-5, 77-105 are rejected under 35 U.S.C. 103(a) as being unpatentable over Minoru Kuroda et al JP 58-140013 ('JP 013) (see entire translation) in view of Grollier et al US Patent 4,767,618 (Grollier II), as applied to claims 1-5, 77-86, 95-101 and further in view of Grollier US Patent 4,880,621 (Grollier III), Briggs et al US Patent 5,871,754.

11. The teaching of JP '013 and Grollier II, are discussed above. Their combined teachings fail to explicitly teach the use of butylated hydroxytoluene as an antioxidant, citric acid and hydrochloride acid as pH modifiers, and EDTA as the chelator.

12. Grollier III is essentially the same teachings as Grollier II, except that it also sets forth that antioxidants such as butyl hydroxytoluene and butyl hydroxyanisole are art recognized equivalents (see col 8, lines 42-44; col 9, lines 43-45).

13. Briggs is merely used to show that allantoin oil-in-water emulsions that chelating agents such as EDTA are among conventional adjuvants used in oil-in-water emulsion systems (see col 10, lines 45-col 11, lines 10).

14. The teachings of Kuroda, Grollier, and Briggs are considered to be in the same field of endeavor, because they all provide for topical administration of oil-in-water emulsion systems.

15. It has been held that the selection of known material based on its suitability for its intended use supported a *prima facie* obviousness determination in *Sinclair & Carroll co. V. Interchemcial Corp.*, 325 U.S. 327, 65 USPQ 297 (1945). Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the JP '013 emulsions by adding cosmetic components of interest including oil retention

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agents such as beeswax, emollients such as cetyl alcohol, herbal components of choice such as chamomile or St. John's wort, and other topical adjuncts such as preservatives as taught and pH modifiers including citric acid, antioxidants such as butylhydroxytoluene, and a chelating agent such as EDTA, as taught by Grollier II and III, and further exemplified by Briggs.

16. The ordinary skill in the art would have had a reasonable expectation of success in combining the above recited components, since it has been reasoned that reading a list and selecting a known compound to meet known requirements is no more ingenious than selecting the last piece to put in the last opening in a jig-saw puzzle. *Sinclair & Carroll co.*, 325 U.S. at 335, 65 USPQ at 301. Thus, since all elements of the instant claims are taught in the cited references to be employed in oil-in-water emulsion systems combining them for their own intended use would have been *prima facie* obvious.

17. Finally, the question of whether a particular parameter can be optimized or not is addressed in *In re Antoine*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). Accordingly, absence of showing unexpected results, discovery of an optimum value of a variable in a known invention is obvious when parameter optimized was recognized to be a result-effective variable. Therefore, Examiner views optimization of the amounts of the instant ingredients is well within the level of ordinary skill in the art and a matter of routine experimentation.

Conclusion

No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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PRIMARY EXAMINER